NEWSLETTER

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Intellectual Property Group
Healthcare Group

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Proposed Pharmaceutical Affairs Act Amendment Regarding Patent-Approval Linkage System

On August 20, 2020, the Ministry of Food and Drug Safety ('**MFDS**') announced a proposed amendment to the Pharmaceutical Affairs Act ('**PAA**') aimed to address certain deficiencies in the Patent-Approval Linkage System that went into effect in 2015. Key features of the proposed amendment may be summarized as follows.

1. Enforcement Rules to Specify Eligibility Criteria for Patent Listing (Article 50-2, Paragraph 6 of the Proposed Amendment)

The current PAA does not clearly explain the requirements for patents to be listed under the Patent-Approval Linkage System, and the lack of clarity has posed difficulties for original drug companies in selecting patents for listing. The proposed amendment addresses this concern by delegating the MFDS to establish enforcement rules to clarify the examination criteria regarding which types of patents may be listed and the eligibility requirements (e.g., the patent be directly relevant to the drug dossiers) and relevant documentation guidelines. Subsequent rulemaking activities therefore are expected and should be monitored.

2. Protection of First Generic Exclusivity Through Restriction on Patent De-listing (Article 50-3, Paragraph 5 of the Proposed Amendment)

Under the current PAA, if a patent is removed from the drug-patent list after first generic exclusivity has been granted, the first generic exclusivity cannot be enforced against follow-on products for which an application for marketing approval has been filed on or after the date of de-listing. The proposed amendment aims to address this concern by restricting de-listing of patents once first generic exclusivity has been applied for until the first generic exclusivity expires.

3. Patent Listing Fee Exemption If De-Listing Is Restricted Due To First Generic Exclusivity (Article 82-2, Paragraph 1 of Proposed Amendment)

Patent listing fee will be waived for any patent that has not been de-listed due to first generic exclusivity despite the market approval holder's request for de-listing.

4. Clarification of Scope of Follow-On Drugs Subject to First Generic Exclusivity (Article 50-9, Paragraph 1 of the Proposed Amendment)

The proposed amendment clarified that follow-on drugs that will be blocked by first generic exclusivity are those approved on or after the date of application for first generic exclusivity. The proposed amendment aims to address the current PAA's failure to specify the applicable timing for the sales ban implemented by first generic exclusivity.

The MFDS will receive comments regarding the proposed amendment until October 19, 2020.

Please contact Lee & Ko for any inquiries regarding the above. Lee & Ko has market-leading expertise and extensive experience in relation to the patent-approval linkage system, as the author of the MFDS' Handbook on Patent-Approval Linkage System.

For more information pertaining to this newsletter, please contact the attorneys identified on the left.

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